ISRCTN40519356 https://doi.org/10.1186/ISRCTN40519356

Protection against Pneumococcal infection in children with T1DM

Submission date
22/07/2013

Recruitment status
No longer recruiting

Registration date
22/07/2013

Overall study status
Completed

Last Edited
10/03/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Children and young people with diabetes may be at a higher risk of getting certain infections. These infections include those caused by a bacterium called the pneumococcus which can cause pneumonia, meningitis and ear infections. In the UK it is recommended that all older children with diabetes are given a vaccine against the pneumococcus bug called Pneumovax (or PPS23 for short). However it is not actually known how well PPS23 protects against infection in children of any age. This study is looking at the use of an alternative vaccine against pneumococcus called Prevenar13 (or PCV13). PCV13 is already given routinely to all babies in the UK and also to children under 5 years of age with diabetes (if they have missed the vaccine as a baby). PCV13 is known to be a safe vaccine and to work well in these age groups. It is therefore expected that the PCV13 vaccine will also protect in older children (6-17 years of age) but there is actually not much information on the immune response or how long it lasts in older children.

Who can participate?
Children aged 6-17 with type 1 diabetes.

What does the study involve?
At the first visit, participants are told what the study involves and are asked to give their consent if they are happy to take part. Basic details about the child's previous immunisations and any relevant medical conditions are then collected. Samples of blood are taken (if possible at the same time as any routine annual blood tests) to check antibody levels. A local anaesthetic cream or cold spray is used to to help prevent any pain. After that a single dose of PCV13 vaccine is given and the child then monitored for 15 minutes. The child is asked, with help from their family if needed. To record their daily temperature or any reaction in a diary card for the next 7 days. Each participant is asked to return for a repeat blood test at 3 months and 1 year later. Where possible, these samples are taken at the same time as the routine annual blood tests.

What are the possible benefits and risks of participating?
In this study the child would receive a single dose of PCV13 vaccine to provide protection against pneumococcal infection. This would not normally have been given to the child but would be expected to increase immunity against these bugs. The study provide the opportunity for the family to know whether the child is protected against most of the pneumococcal bacteria in the

vaccine after immunisation. Like all medicines, the vaccine may cause side effects in some individuals. More common side-effects (1-10% of those vaccinated) include headaches, fever, feeling generally unwell, shivering, fatigue, loss of appetite and local reactions (e.g. redness, swelling, pain, bruising and hardness). These events are generally mild and resolve within a few days. As with all vaccines, there is the very small possibility of a severe allergic reaction (anaphylaxis).

Where is the study run from?
Oxford University Hospitals NHS Foundation Trust and Royal Berkshire NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
July 2013 to December 2017

Who is funding the study?
Oxfordshire Health Services Research Committee (OHSRC) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2013-001024-19

Protocol serial number
14963

Study information

Scientific Title

An open label single-arm study of the immunogenicity and reactogenicity of a 13-valent pneumococcal conjugate vaccine (Prevenar13®) given to children with type 1 diabetes mellitus who have not previously received a primary schedule of immunisation with pneumococcal conjugate vaccines in infancy

Study objectives
There are two types of pneumococcal vaccine plain polysaccharide (PPS) and conjugate (PCV) vaccines. PPS do not induce immune responses under 2 years of age and do not induce immunological memory for the pneumococcus furthermore in adults PPS may reduce the response to subsequent doses of pneumococcal vaccine. It is uncertain whether this happens in children. PCVs were developed to overcome the limitations of PPS vaccines and are widely used in children under 5 years of age. However, there remains uncertainty about which pneumococcal vaccines are best to use in older children (over 5 years of age) who are at risk of pneumococcal disease. Furthermore there are limited data on both the response to PCVs in this age group and whether prior immunisation with PPS results in a reduced immune response. We plan to assess baseline immunity and response to a PCV (covering 13 types of pneumococcus - PCV13) in 50 children over 5 years of age with T1DM and assess this in relation to whether they have or have not previously received PPS. The children will be recruited from a group of over 250 children with T1DM under the care of the diabetes team at Oxford University Hospitals NHS Trust. The immune response will be assessed at baseline, 3 months and 12 months after immunisation. This will provide novel data on the initial immune response in this age group, persistence of immunity and the effect of PPS. This will be important data against which to consider the use of PPS and PCVs in this and other high risk populations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 02/07/2013, ref: 13/SC/0199

Study design
Non-randomised interventional trial; Design type: Prevention

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Primary Intervention, a single dose of 13-valent pneumococcal conjugate vaccine (PCV13)

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
13-valent pneumococcal conjugate vaccine (Prevenar13®)

Primary outcome(s)
The proportion of children with vaccine pneumococcal serotype specific (SpVS) antibody concentration. The immune response will be assessed at baseline, 3 months and 12 months after immunisation.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Diagnosis of T1DM and being followed in the Oxfordshire Childrens Diabetes Service
2. Aged from 6-17 years old
3. Parent/legal guardian willing and able to give informed consent
4. No previous immunisation with a pneumococcal conjugate vaccine (PCV)
5. Willing to allow the General Practitioner to be notified of participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Known allergic reaction to the vaccine antigen or any of the excipients
2. Bleeding diathesis or condition associated with prolonged bleeding time that would contraindicate intramuscular injection

Date of first enrolment
20/08/2013

Date of final enrolment

17/12/2015

Locations

Countries of recruitment
United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford
United Kingdom
-

Study participating centre
Royal Berkshire NHS Foundation Trust
Berkshire
United Kingdom
-

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Oxfordshire Health Services Research Committee (OHSRC) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No